REMARKS

Claims 1-37 are pending. Claims 1-23 and claims 27-29 have been canceled as drawn to non-elected subject matter. Claims 24-26 and claims 30-37 remain under consideration, and stand rejected in the Office Action mailed February 12, 2003.

I. Rejections 35 U.S.C. § 112, second paragraph

The Patent Office has rejected claims 24-26 and 30-37 under 35 U.S.C. § 112, second paragraph. With regard to claim 24, the terms "inactive," cell death domain, "gene", and "effecting" are deemed unclear. The amendments to the claims are believed to make it clear that the claim is directed to a DNA sequence encoding a protein which comprises an "inactive cell death domain" (a term defined in the specification at page 12, lines 1-5, and discussed at length in context on pages 11-13 of the specification) which is "caused" to be expressed.

The Patent Office has objected to the use of the term "derived" in claims 25 and 31, and all subsequent recitations thereof. The term "derived" is an often-used term in the molecular biology arts, with a meaning well-known to persons of ordinary skill in the art, and furthermore is used consistently in the specification in a manner consistent with this customary meaning. For example, the specification at page 5, lines 26-30 discusses a "derived" silencer transgene, page 8, lines 7-16 discusses how a particular vector is "derived", page 30, lines 17-20 discusses gene regions "derived" from two different cucumovirus and lines 26-30 discusses sequences "derived" from the Cmv2b gene, page 31, lines 11-13 describes sequences "derived" from Tav2b. Furthermore, the titles of the cited references themselves indicate the use of this term in the art

(see for example, Kumagai, et al., Cytoplasmic Inhibition of Carotenoid Biosynthesis With Virus-Derived DNA"). Applicant therefore respectfully submits that the term "derived" is not only a term readily understandable to a person having ordinary skill in the art, but is also used in a number of places in the specification which make clear this meaning in the context of the present claims. Applicant therefore respectfully submits that the term "derived" as used in the present claims in connection with the invention described in the present specification is not unclear.

The term "the Avr gene" was found to lack antecedent basis in claim 25. While the term "Avr gene" does appear in claim 24 from which claim 25 depends, and thus antecedent basis is present, this term has now been replaced in the claims, rendering this rejection moot.

The Patent Office has objected to the use of the term "chimera" in claims 26 and 32. The claims have been amended to specify a "molecular" chimera, a term of art referring to a fusion of two sequences, such as DNA sequences or amino acid sequences not found together in nature. While the distinction noted in the Office Action between "recombinant" and "physical hybrid" is not clear to the Applicant (in view of the fact that the reference in the claims is to a gene, which cannot be physically hybridized as a plant can), Applicant submits that the term "molecular chimera" presently appearing in the claims is sufficiently descriptive of the physical relationship between the portions of the DNA sequence recited in claims 26 and 32 to satisfy the definiteness requirements of 35 U.S.C. § 112, second paragraph.

The Patent Office has objected to the use of the term "plant active" promoter in claim 30. Applicant submits that this is a well-known term of art that is readily understood by persons of ordinary skill in the art to mean a promoter that is active in a plant. Such a promoter may be a plant promoter (i.e., a promoter that occurs in a plant genome in nature), or a promoter from

another kingdom which nonetheless promotes expression of genes in a plant (for example, the CAMV 35S promoter, which is a viral promoter that is active in a plant). Whether or not the promoter is "activated" by the plant does not appear to be relevant, in the present context, as the claims clearly recite promoters which are stably integrated into a plant genome, and whether or not the promoter is activated by the plant in some undefined way does not make it any more or less a "plant active promoter," which as has been said is a term well known in the art. Applicant therefore respectfully submits that this objection is misplaced and requests that it be withdrawn.

The Patent Office has objected to the use of the term "propagating part" in claim 36. This term has been replaced with the term "propagule", a conventional botanical and horticultural term meaning any portion of a plant, usually a vegetative portion such as a bud stem, root, or stem or root section, that aid in the disbursal of the species and from which a new individual may develop (i.e., by which the plant may be propagated). Applicant believes that this clarifies the meaning of claim 36.

In view of the foregoing remarks and the amendments to the claims, Applicant respectfully submits that claims 24-26 and 30-37 are in compliance with the requirements of 35 U.S.C. § 112, second paragraph, and request reconsideration and withdrawal of these rejections.

II. Claim Rejections Under 35 U.S.C. § 101

Claims 35 and 36 have been rejected under 35 U.S.C. § 101 because the seeds, or propagating parts of, the transgenic plants recited in the those claims "are subject to segregation of transgenes." Office Action on page 4. The Patent Office thus asserts that since no selection of the seed or propagules is recited, not all the progeny would contain the transgene. While this

could be said of the seed of claim 35 (the result of sexual reproduction and thus subject to gene segregation), it is unlikely to be the case with a propagule, which is a vegetative part of the plant, absent some form of mutation giving rise to a tissue chimera. Nonetheless, both claims 35 and 36 have now been amended to specifically recite that the seed and propagules claimed contain the DNA sequence of interest of claims 24, 25 or 26. Applicant respectfully submits that the claims as amended do not read on a product of nature, and request reconsideration and withdrawal of this rejection.

III. Claim Rejections 35 U.S.C. §112, first paragraph - Written Description

The Patent Office has rejected claims 23-26 and 30-37 under 35 U.S.C. §112, first paragraph as containing subject matter which is not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors at the time the application was filed had possession of the claimed invention. Office Action at pages 4-5. The Patent Office maintains that "Applicants recite various functional components, but give no information on the structure(s) required for the function(s)," citing University of California v. Eli Lilly, 43 USPQ 2d 1398 (Fed. Cir. 1997). Applicant respectfully submits that this rejection is misplaced.

The claims specifically recite DNA sequences encoding Avr proteins, and particular domains thereof. This is not a functional description of DNA, but rather a recitation of a class of known DNA sequences. The R-Avr gene system is well known, well defined, and extensively published in the prior art. See, for example, specification at page 2, starting at line 17 through page 6, line 20, where "Avr" genes and proteins are discussed with regard to the identifying

characteristics of the genus and specifically by citation to specific references disclosing specific sequences of specific Avr genes and Avr proteins. This is not at all the same as the situation in the University of California v. Eli Lilly case, where the applicant simply claimed a cDNA "encoding insulin" – in the present case the term refers to a well-published and specific class of known gene sequences. Furthermore, the gene domains in question are very specifically defined, starting at page 11, line 25. Thus, contrary to the assertions of the Patent Office at page 5 of the Office Action, there is an abundant description of the structural and physical characteristics of the claimed composition, placing a person of ordinary skill in the art in possession of the genus claimed at the time this application was filed. Applicants respectfully request that this rejection be reconsidered and withdrawn.

IV. Claim Rejection 35 U.S.C. § 112, first paragraph - Enablement

The Patent Office has rejected claims 24-26 and 30, 31 and 33-37 under 35 U.S.C., §112, first paragraph, as the specification allegedly does not reasonably provide enablement for "any two domain Avr gene, or any plant or any pathogenic organism, or the broad scope of the claims." Office Action, page 6. The Patent Office asserts that the infecting of a given plant with a given plant pathogen is unpredictable (citing Agrios, Plant Pathology, 3rd edition). The Agrios article, however, does not support this assertion. The article states that "pathogens differ with respect to the kinds of plants that they can attack, with respect to the organs and tissues that they can infect, and with respect to the age of the organ or tissue of the plant on which they can grow." Agrios (page number obscured in the copy provided by the Patent Office). This statement, and the subsequent discussion simply states what is well known in the art – that there

is a wide variety of plant pathogens that attack plants in a wide variety of ways and that often pathogens are plant, and even tissue specific. This does not indicate that there is unpredictability in the art as to how a known pathogen will attack a known susceptible plant, nor that it was beyond the skill of the person of ordinary skill in the art to determine whether or not a particular plant is susceptible to a particular pathogen. In fact, screening novel crop and horticultural plants (novel hybrids, novel transgenic plants, newly discovered or naturally occurring mutants, etc.) against known plant pathogens is a long-standing and routine practice in the horticultural and agricultural arts. While such screening may involve handling a large number of pathogens and a large number of plants, it is something that is done routinely with new plant varieties being evaluated for the market (Applicant notes, for example, that an application for a Plant Variety Protection Certificate requires a statement regarding the susceptibility or resistance to the most common pathogens associated with that crop. See, for example, the general requirements for a distinguishing character as provided by the USDA Plant Variety Protection Office at www.ams.usda.gov/science/pvpo/forms/guidelinesB.htm (a printout of which is enclosed for the Examiner's convenience).

The Patent Office has not disputed that the present specification enables a person of ordinary skill in the art to construct and use a variety of two- domain Avr gene constructs, and has in essence made an "undue trial and error" enablement rejection, a standard for enablement which has been rejected expressly by the Federal Circuit, its precedent courts, and the Board of Patent Appeals and Interferences. W.L. Gore v. Garlock, 220 USPQ 303, 316 (Fed. Cir. 1983), cert denied 469 U.S. 851 (1984) ("[rejection based on trial and error experimentation standard] was error. Assuming some experimentation was needed, the patent is not invalid because of the need for experimentation."); see also In re Angstadt and Griffin, 120 USPQ, 214, 218 (CCPA

1976) (undue experimentation is that which would "require ingenuity beyond that to be expected of one of ordinary skill in the art."); Ex parte Jackson, 217 USPQ 804, 807 (BPAI 1982) ("The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed to enable the determination of how to practice a desired embodiment of the invention claimed."). Thus, the mere fact that a person of ordinary skill in the art would be required to test a plant transformed by routine methods with gene sequences selected from a well-defined group described in the specification, using methods well known and routine in the art, might be required to undertake a large number of potentially lengthy and tedious experiments, is not, in and of itself, sufficient to show that the specification is not enabling.

To be enabling under §112, a patent must contain a description that enables one skilled in the art to make and use the claimed invention. Raytheon Company v. Roper Corporation, 220 USPQ 592, 599 (Fed. Cir. 1983) cert denied, 469 US 835 (1984). The Patent Office has not disputed that the specification provides detailed means for selecting and combining appropriate gene sequences, stably transforming plants with these sequences, and testing the resulting plants for disease resistance. The Patent Office has provided no evidence that the methods and techniques disclosed in the specification, combined with the knowledge in the possession of a person of ordinary skill in the art would not permit such a person from practicing the invention throughout the entire scope of the claims. The burden of providing such evidence resides with the PTO. In re Piasecki, 223 USPQ 785, 788 (Fed. Cir. 1984). Applicant therefore respectfully submits that the specification is, in fact, enabling for the full scope of the claims and that this rejection is not warranted. Applicant respectfully requests that it be reconsidered and withdrawn.

CONCLUSIONS

In light of the present amendments and foregoing remarks, Applicant respectfully submits that the claims as amended are in condition for allowance and requests that the pending rejections be reconsidered and withdrawn. Favorable action on the claims is earnestly solicited.

Respectfully submitted,

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July 14, 2003 By 

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Plant Variety Protection Office - Guidelines Exhibit B
Statement of Distinctness

To produce a Statement of Distinctness the applicant can follow the below steps:

(1a) State the **most similar** previously existing variety, varieties, or identifiable group of varieties; or,

(1b) State all the previously existing varieties known for a crop. Generally, this can only be one for a newly identified crop.

(2) State the character or characters that clearly distinguish the applicant's variety from the varieties stated in step 1 (i.e., the most similar variety or varieties).

(3) State the qualities or quantities of the character(s) referenced in step 2. Note the character state must be provided for the application variety and the most similar variety or varieties. Please see *Examples of Statements of Distinctness*.

General Requirements for a Distinguishing Character

Differences in quantitative characters such as plant size, seed size, and maturity, that are not obvious and detectable without a direct comparison, must be supported by evidence provided by the applicant. The evidence must be given as numerical data obtained from at least 2 trials. Please see the *Guidelines for Presenting Evidence in Support of Variety Distinctness*.

Distinction based on differences in color needs to be referenced with a standard such as the Royal Horticultural Society Colour Chart or the Munsell Book of Color, unless dramatic (i.e., red vs. green). Color chart measurements must be conducted in two or more localities or growing seasons.

Distinction based on differences in disease reaction needs to be supported with data or results from at least 2 trials that were conducted in two or more localities or growing seasons, unless dramatic (i.e., immune vs. highly susceptible); or the presence or absence of a gene known to elicit the reaction must be stated. When the causal agent has been demonstrated or identified, the source of the disease must be provided. Also, the disease reaction needs to be referenced to the causal agent or organism including the race, strain, or pathotype where appropriate. If the causal agent has not been demonstrated or identified, the source of the disease or inoculant must be provided.

Differences in yield cannot be used as a basis for distinction because yield is a highly complex character. Sub-characters that contribute to differences in yield can be used as a basis for distinction.

Improvements in uniformity (by reducing the standard variation) are not sufficient to assess distinction.

Guidelines f r Pres nting Evid nc in Supp rt of Variety Distinctne s

Differences in quantitative characters such as plant size, seed size, maturity and any

difference not obvious must be given as numerical data obtained from similar comparisons with a statistical analysis showing the degree of significance. The comparison must be conducted in at least two locations or two growing periods.

The following information is required as part of the statistical analysis:

(1) Provide data or results from at least 2 trials for comparison of a differentiating characteristic, conducted in two or more localities or growing seasons with the results analyzed separately clearly demonstrating repeatability (do not pool your data);

(2) The location of each trial. The planting, harvesting, and comparison dates for each trial. The number of plant in each trial. The sample size or number of plants (or plant parts) for each comparison;

(3) Mean or average value of the differentiating characteristic for each variety in the comparison.

(4) Some measure of the range of observed values for each variety in the comparison, such as the standard deviation, 95% confidence intervals, the actual range observed values from minimum to the maximum, or a histogram or box plot, which are helpful in determining the validity of any comparisons;

(5) Name of the specific statistical analysis used (e.g., T-test, specific "LSD" procedure, ANOVA, or the like);

(6) Citation of the actual statistic and the probability value (if a T-test was used, provide the actual T-value, as well as the probability value corresponding to it);

(7) Evidence that the analysis is appropriate in this case (e.g. if the distribution was not a normal distribution, that the analysis was non-parametric, e.g. Mann-Whitney U-test, or that the data were appropriately transformed), include any factors that prevented the normal distribution and/or confidence of the data.

Examples of Statements of Distinctness

'Variety A' is most similar to 'Variety B'; however, 'Variety A' has a darker leaf color than 'Variety B' (140B vs. 140A and 143B vs. 143A RHS, respectively).

'Variety A' is most similar to 'Variety B'; however, 'Variety A' has a lighter pod color than 'Variety B', (137B vs. 193A RHS, respectively).

'Variety A' is most similar to 'Variety B'; however, 'Variety A' has the *er* gene conferring resistance to *Erisyphe pisi* (powdery mildew), whereas 'Variety B' lacks the *er* gene and is susceptible.

'Variety A' is most similar to 'Variety B'; however, 'Variety A' carries the *mo* allele for resistance to bean yellow mosaic virus and is resistant, whereas 'Variety B' carries the *Mo* dominant allele for susceptibility and is susceptible.

'Variety A' is most similar to 'Variety B'; however, 'Variety A' is more resistant to *Erisyphe pisi*, which causes powdery mildew, than 'Variety B', 3.0 vs. 5.5 on a 1-9 scale with 1 being highly resistant and 9 being highly susceptible.

'Variety A' produces 2 to 3 flowers per node, whereas 'Variety B' only produces 1 to 2 flowers per node.

'Variety A' is most similar to 'Variety B'; however, 'Variety A' flowers 6 days earlier than 'Variety B' (50 vs. 56 days, respectively).

'Variety A' is most similar to 'Variety B'; however, 'Variety A' has a larger seed weight than 'Variety B' (2500 vs. 3000 seeds/lb., respectively).

'Variety A' is most similar to 'Variety B'; however, 'Variety A' has a brown hilum, whereas 'Variety B' has a black hilum.

'Variety A' is most similar to 'Variety B'; however, 'Variety A' differs from 'Variety B' in plant height (219 vs. 178 cm) and ear height (90 vs. 69 cm).

'Variety A' is most similar to 'Variety B'; however, 'Variety A' differs from 'Variety B' in leaf angle (14 vs. 28 degrees, respectively) and silk color, salmon vs. green (Munsell 2.5R 4/8 vs. 2.5 GY 8/6, respectively).

'Variety A' is most similar to 'Variety B' and 'Variety C'; however, 'Variety A' is 7 days earlier to bloom than 'Variety B' and 4 days later to bloom than 'Variety C'.

'Variety A' is most similar to 'Variety B' and 'Variety C'. 'Variety A' has a lower lint percent (35.0 vs. 37.6%), lower lint index (6.6 vs. 7.9 g lint/100 seeds), higher stelometer (33.2 vs. 30.2 g/tex) and higher 2.5% span length (1.37 vs. 1.32) than 'Variety B'. 'Variety A' has a lower lint index (6.6 vs. 7.3 g lint/100 seeds) and a lighter boll (3.2 vs. 3.4 g) than 'Variety C'.

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